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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/627,775	07/28/2000	Mark I. Greene	UPN-3832	3099

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 01/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/627,775

Applicant(s)

Greene

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 11, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-16, 18-30, and 34-48 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-16, 18-30, and 34-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9 20) ☐ Other:

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## **DETAILED ACTION**

### ***Specification***

1. Claims 1, 17, and 31-33 have been cancelled without prejudice towards further prosecution. Claims 2, 18, and 34 have been amended. The pending claims are 2-16, 18-30, and 34-48.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-16, 18-30, and 34-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 18, and 34 are rejected over the recitation of the phrase, "capable of".

Regarding claims 2, 18, and 34, the phrase "capable of" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

### ***Claim Rejections - 35 USC § 103***

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-16, 18-30, and 34-48 are rejected under 35 U.S.C. 103 (a) over Yamaguchi et al. (Journal of Biological Chemistry, (1998), Vol. 273 (No: 9), pages 5117-5123) in view of Green et al. (PCT International Publication NO: WO 98/53842) (December 3, 1998).

Yamaguchi et al teach a method for inhibiting osteoclastogenesis, and bone loss by reciting that osteoclastogenesis inhibitory factor (OCIF) is a heparin-binding secretory glycoprotein that belongs to the tumor necrosis factor (TNF) family. OCIF is present both as a ~ 60 kDa monomer and a disulfide-linked homodimer. Their result show that the N-terminal portion of OCIF containing domains 1-4, which have structural similarity to the extracellular

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domains of the TNFR family proteins, is sufficient to inhibit osteoclastogenesis (Abstract, Figures 1-2, page 5119).

Yamaguchi et al do not teach the peptide inhibitors with 3-18, 1-6, 1-3, and 1-2 amino acids.

Green et al teach the peptide inhibitors with 3-18, 1-6, 1-3, and 1-2 amino acids (Page 4, lines 21-36, and page 5, lines 1-19). Green et al also teach the composition of an inhibitor which has a peptide of 3-18 amino acid residues corresponding in primary sequence to a binding loop of a TNF-R superfamily member with all the limitation of the claimed invention. Moreover, Green et al teach an inhibitor which has the identical skeletal structure with a peptide of 1-6 amino acids, at least one of which is a hydrophobic amino acid, an aromatic moiety or a heteroatomic moiety which has all the limitations of the claimed invention (Page 23, lines 25-36, and page 25, lines 1-14, and page 27).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the composition of an inhibitor which has a peptide of 3-18 amino acid residues corresponding in primary sequence to a binding loop of a TNF-R superfamily member of Green et al. in the method of osteoclastogenesis inhibition of Yamaguchi et al., since Green et al. state, "The present invention relates to peptides and peptide analogues designed from a binding loop of a member of the tumor necrosis factor receptor (TNF-R) superfamily, which is involved in binding interactions with its ligand. In particular, it relates to cyclic peptides and peptide analogues designed from three specific binding loops in domains 2

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and 3 of TNF-R which inhibit tumor necrosis factor (TNF) binding to its cellular receptors, methods of designing similar peptides and peptide analogues, and methods of using such compounds to inhibit the biological activities of TNF, thereby antagonizing its undesirable clinical effects” (Introduction, lines 5-15). Moreover, Yamaguchi et al provides motivation as Yamaguchi et al state, “The N-terminal portion of OCIF containing domains 1-4, which have structural similarity to the extracellular domains of the TNFR family proteins, is sufficient to inhibit osteoclastogenesis (Abstract, lines 12-15)”. By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the composition of an inhibitor which has a peptide of 3-18 amino acid residues corresponding in primary sequence to a binding loop of a TNF-R superfamily member of Green et al. in the method of osteoclastogenesis inhibition of Yamaguchi et al. in order to achieve the express advantages, as noted by Yamaguchi et al., of an invention that reveals the effectiveness of the N-terminal portion of OCIF containing domains 1-4, which have structural similarity to the extracellular domains of the TNFR family proteins, to inhibit osteoclastogenesis.

***Response to Amendment***

6. In response to amendment, all previous 112 (first and second paragraph) and 102 (b) rejection have been withdrawn. However, a new 112 (second paragraph) rejection has been included and 103 (a) rejection has been maintained with proper explanation of the motivation statements.

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***Response to Arguments***

7. Applicant's arguments filed on November 11, 2001 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant also argues that there is no motivation to combine the references. This argument is not persuasive. The motivation statements from both the references have now been included in the office action to make the obviousness rejection more clear.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

**Arun Chakrabarti**  
**Patent Examiner**  
**Art Unit 1655**  
**January 10, 2002**

  
**W. Gary Jones**  
**Supervisory Patent Examiner**  
**Technology Center 1600**